

bill, trying to address that. It has been a plague on my State like it has been on so many others.

He really gave people freedom to bring the best ideas and put all the best ideas together with both sides. He could always compromise without compromising his values and his principles. He said: If there is a way for both sides to win, let's find a way for both sides to win.

Mr. Speaker, I know the gentleman has yielded me as much time as I may consume. If I consumed everything to say what is good about you and the value you are to this institution, I would be here all afternoon because you have really made an impact on this institution. You have made an impact upon our conference.

I think people on both sides of the aisle have said your service here has made a difference, not for Congress, but through your service in Congress and for the country, and I thank you for that. We are going to miss you, and I wish you Godspeed as you move forward.

□ 1400

Mr. PALLONE. Mr. Speaker, I have no additional speakers on this side, and I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield myself a minute or so here to thank my friend, the gentleman from Kentucky (Mr. GUTHRIE) who, as you all know, is a terrific legislator, a bright mind. And he, too, has served his country with distinction in uniform and here in the Congress, and he will have a great future going forward in this institution.

Mr. Speaker, I yield such time as he may consume to the gentleman from Georgia (Mr. CARTER).

Mr. CARTER of Georgia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of H.R. 5758, the Ceiling Fan Improvement Act. This legislation will update the energy efficiency standards for ceiling fans manufactured after January 21 of this year.

We are here today because the existing energy and efficiency standards for ceiling fans was insufficient to meet the characteristics of ceiling fans being manufactured.

Specifically, the energy conservation standards finalized in January 2017 didn't properly account for the different types of air flow of large ceiling fans. Therefore, the result of not changing this law could be the removal of large ceiling fans from the market because they won't be in compliance.

This issue is a great example of how now nuanced and challenging some of these issues and topics can be here in Congress. Thanks to the leadership of my good friend, Congressman GUTHRIE, and that of Chairwoman SCHAKOWSKY, we are now one step closer to getting this fix across the finish line.

Mr. Speaker, I thank my colleagues on the Committee on Energy and Commerce for their work on this legislation

and for the bipartisan efforts to get it here, and I urge all of my colleagues to support this legislation.

Mr. PALLONE. Mr. Speaker, I reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I have no other speakers on my side of the aisle. It is good legislation, bipartisan. It should become law. I urge its passage, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I would urge support for this legislation, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 5758.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. PALLONE. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3 of House Resolution 965, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this question are postponed.

MEDICAL MARIJUANA RESEARCH ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3797) to amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3797

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Marijuana Research Act".

SEC. 2. FACILITATING MARIJUANA RESEARCH.

(a) PRODUCTION AND SUPPLY.—The Secretary of Health and Human Services—

(1) until the date on which the Secretary determines that manufacturers and distributors (other than the Federal Government) can ensure a sufficient supply of marijuana (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), as amended by section 8) intended for research by qualified marijuana researchers registered pursuant to paragraph (3) of section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), as added by section 3, shall—

(A) continue, through grants, contracts, or cooperative agreements, to produce marijuana through the National Institute on Drug Abuse Drug Supply Program;

(B) not later than one year after the date of enactment of this Act, act jointly with the Attorney General of the United States to establish and implement a specialized process for manufacturers and distributors, notwithstanding the registration requirements of section 303 of such Act (21 U.S.C. 823), to supply qualified marijuana researchers with marijuana products—

(i) available through State-authorized marijuana programs; and

(ii) consistent with the guidance issued under subsection (c); and

(C) not later than 60 days after the date of enactment of this Act, jointly convene with the Attorney General a meeting to initiate the development of the specialized process described in subparagraph (B); and

(2) beyond the date specified in paragraph (1), may, at the Secretary's discretion, continue—

(A) through grants, contracts, or cooperative agreements, to so produce marijuana; and

(B) to implement such specialized process.

(b) REQUIREMENT TO VERIFY REGISTRATION.—Before supplying marijuana to any person through the National Institute on Drug Abuse Drug Supply Program or through implementation of the specialized process established under subsection (a)(1)(B), the Secretary of Health and Human Services shall—

(1) require the person to submit documentation demonstrating that the person is a qualified marijuana researcher seeking to conduct research pursuant to section 303(f)(3) of the Controlled Substances Act, as added by subsection (d) of this section, or a manufacturer duly registered under section 303(l) of the Controlled Substances Act, as added by section 3 of this Act; and

(2) not later than 60 days after receipt of such documentation, review such documentation and verify that the marijuana will be used for such research (and for no other purpose authorized pursuant to this Act or the amendments made by this Act).

(c) GUIDANCE ON USE OF STATE-AUTHORIZED MARIJUANA PROGRAMS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidance related to marijuana from State-authorized marijuana programs for research.

(d) RESEARCH.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended—

(1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively;

(2) by striking "(f) The Attorney General" and inserting "(f)(1) The Attorney General";

(3) by striking "Registration applications" and inserting the following:

"(2) Registration applications";

(4) in paragraph (2), as so designated, by striking "schedule I" each place that term appears and inserting "schedule I, except marijuana,";

(5) by striking "Article 7" and inserting the following:

"(4) Article 7"; and

(6) by inserting before paragraph (4), as so designated, the following:

"(3)(A) The Attorney General shall register the applicant to conduct research with marijuana if—

"(i) the applicant is authorized to dispense, or conduct research with respect to, controlled substances in schedule I, II, III, IV, or V;

"(ii) the applicant is compliant with, and authorized to conduct the activities described in clause (i) under, the laws of the State in which the applicant practices; and

"(iii) in the case of an applicant pursuing clinical research, the applicant's clinical research protocol has been reviewed and authorized to proceed by the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

"(B) An applicant registered under subparagraph (A) shall be referred to in this section as a 'qualified marijuana researcher'.

"(C)(i) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this paragraph, the Attorney General shall approve or deny the application.

“(ii) For purposes of clause (i), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under subparagraph (A) are satisfied.

“(iii) In the case of a denial under clause (i), the Attorney General shall provide a written explanation of the basis for the denial.

“(D) The Attorney General shall grant an application for registration under this paragraph unless the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

“(i) The applicant’s experience in dispensing, or conducting research with respect to, controlled substances.

“(ii) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

“(iii) Compliance with applicable State or local laws relating to controlled substance misuse or diversion.

“(iv) Such other conduct which may threaten the public health and safety.

“(E)(i) A qualified marijuana researcher shall store marijuana to be used in research in a securely locked, substantially constructed cabinet.

“(ii) Except as provided in clause (i), any security measures required by the Attorney General for applicants conducting research with marijuana pursuant to a registration under this paragraph shall be consistent with the security measures for applicants conducting research on other controlled substances in schedule II that have a similar risk of diversion and abuse.

“(F)(i) If the Attorney General grants an application for registration under this paragraph, the applicant may amend or supplement the research protocol and proceed with the research under such amended or supplemented protocol, without additional review or approval by the Attorney General or the Secretary of Health and Human Services if the applicant does not change the type of marijuana, the source of the marijuana, or the conditions under which the marijuana is stored, tracked, or administered.

“(ii) If an applicant amends or supplements the research protocol or initiates research on a new research protocol under clause (i), the applicant shall, in order to renew the registration under this paragraph, provide notice to the Attorney General of the amended or supplemented research protocol or any new research protocol in the applicant’s renewal materials.

“(iii)(I) If an applicant amends or supplements a research protocol and the amendment or supplement involves a change to the type of marijuana, the source of the marijuana, or conditions under which the marijuana is stored, tracked, or administered, the applicant shall provide notice to the Attorney General not later than 30 days before proceeding on such amended or supplemental research or new research protocol, as the case may be.

“(II) If the Attorney General does not object during the 30-day period following a notification under subclause (I), the applicant may proceed with the amended or supplemental research or new research protocol.

“(iv) The Attorney General may object to an amended or supplemental protocol or a new research protocol under clause (i) or (iii) only if additional security measures are needed to safeguard against diversion or abuse.

“(G) If marijuana is listed on a schedule other than schedule I, the provisions of paragraphs (1), (2), and (4) that apply to research with a controlled substance in the applicable

schedule shall apply to research with marijuana or that compound, as applicable, in lieu of the provisions of subparagraphs (A) through (F) of this paragraph.

“(H) Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 505(i) of the Federal Food, Drug, and Cosmetic Act or over requirements related to research protocols, including changes in—

“(i) the method of administration of marijuana;

“(ii) the dosing of marijuana; and

“(iii) the number of individuals or patients involved in research.”

SEC. 3. MANUFACTURE AND DISTRIBUTION OF MARIJUANA FOR USE IN LEGITIMATE RESEARCH.

Section 303 of the Controlled Substances Act (21 U.S.C. 823), as amended by section 2, is further amended by adding at the end the following:

“(1) REGISTRATION OF PERSONS TO MANUFACTURE AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE RESEARCH.—

“(1) REGISTRATION OF MANUFACTURERS.—

“(A) IN GENERAL.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General, pursuant to subsection (f)(3) and subject to subparagraph (B) of this paragraph, shall register an applicant to manufacture marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for—

“(i) the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3); or

“(ii) subsequent downstream manufacture by a duly registered manufacturer for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3).

“(B) PUBLIC INTEREST.—The Attorney General shall register an applicant under subparagraph (A) unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the Attorney General shall take into consideration—

“(i) maintenance of effective controls against diversion of marijuana and any controlled substance compounded therefrom into other than legitimate medical, scientific, or research channels;

“(ii) compliance with applicable State and local laws relating to controlled substance misuse and diversion;

“(iii) prior conviction record of the applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; and

“(iv) such other conduct which may threaten the public health and safety.

“(2) REGISTRATION OF DISTRIBUTORS.—

“(A) IN GENERAL.—Beginning not later than the day that is 1 year after the date of enactment of the Medical Marijuana Research Act, the Attorney General shall register an applicant to distribute marijuana (including any derivative, extract, preparation, and compound thereof) that is intended for the ultimate and exclusive use by qualified marijuana researchers for research pursuant to subsection (f)(3) or intended for subsequent downstream manufacture by a duly registered manufacturer for use by qualified marijuana researchers for research pursuant to such subsection, unless the Attorney General determines that the issuance of such registration is inconsistent with the public interest.

“(B) PUBLIC INTEREST.—In determining the public interest under subparagraph (A), the Attorney General shall take into consideration—

“(i) the factors specified in clauses (i), (ii), (iii), and (iv) of paragraph (1)(B); and

“(ii) past experience in the distribution of controlled substances, and the existence of effective controls against diversion.

“(3) NO LIMIT ON NUMBER OF MANUFACTURERS AND DISTRIBUTORS.—Notwithstanding any other provision of law, the Attorney General shall not impose or implement any limit on the number of persons eligible to be registered to manufacture or distribute marijuana pursuant to paragraph (1) or (2).

“(4) REQUIREMENT TO VERIFY USE FOR LEGITIMATE RESEARCH.—As a condition of registration under this section to manufacture or distribute marijuana, the Attorney General shall require the registrant—

“(A) to require any person to whom the marijuana will be supplied to submit documentation demonstrating that the marijuana (including any derivative, extract, preparation, and compound thereof) will be ultimately used exclusively by qualified marijuana researchers for research pursuant to subsection (f)(3) or for subsequent downstream manufacture by a duly registered manufacturer for use by qualified marijuana researchers for research pursuant to such subsection;

“(B) in the case of distribution, to complete, with respect to that distribution, the appropriate order form in accordance with section 308 and to upload such forms to the system used by the Drug Enforcement Administration for such distribution;

“(C) to include in the labeling of any marijuana so manufactured or distributed—

“(i) the following statement: ‘This material is for biomedical and scientific research purposes only.’; and

“(ii) the name of the requestor of the marijuana;

“(D) to limit the transfer and sale of any marijuana under this subsection—

“(i) to researchers who are registered under this Act to conduct research with marijuana or to manufacturers duly registered under this subsection; and

“(ii) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act or for the purposes of further manufacturing of marijuana; and

“(E) to transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

“(5) TIMING.—Not later than 60 days after receipt of a request for registration under this subsection to manufacture or distribute marijuana, the Attorney General shall—

“(A) grant or deny the request; and

“(B) in the case of a denial, provide a written explanation of the basis for the denial.

“(6) DEEMED APPROVAL.—If the Attorney General fails to grant or deny a request for registration under this subsection to manufacture or distribute marijuana within the 60-day period referred to in paragraph (5), such request is deemed approved.”

SEC. 4. TERMINATION OF INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED QUALIFIED MARIJUANA RESEARCHERS.

The Secretary of Health and Human Services may not—

(1) reinstate the Public Health Service interdisciplinary review process described in the guidance entitled “Guidance on Procedures for the Provision of Marijuana for Medical Research” (issued on May 21, 1999); or

(2) create an additional review of scientific protocols that is only conducted for research on marijuana other than the review of research protocols performed at the request of a qualified marijuana researcher conducting

nonhuman research that is not federally funded, in accordance with section 303(f)(3)(A) of the Controlled Substances Act, as added by section 2 of this Act.

SEC. 5. CONSIDERATION OF RESULTS OF RESEARCH.

Immediately upon the approval by the Food and Drug Administration of an application for a drug that contains marijuana (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), as amended by section 8 of this Act) under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and (irrespective of whether any such approval is granted) not later than the date that is 5 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) conduct a review of existing medical and other research with respect to marijuana;

(2) submit a report to the Congress on the results of such review; and

(3) include in such report whether, taking into consideration the factors listed in section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)), as well as any potential for medical benefits, any gaps in research, and any impacts of Federal restrictions and policy on research, marijuana should be transferred to a schedule other than schedule I (if marijuana has not been so transferred already).

SEC. 6. PRODUCTION QUOTAS FOR MARIJUANA GROWN FOR LEGITIMATE, SCIENTIFIC RESEARCH.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

“(j) The Attorney General may only establish a quota for production of marijuana that is manufactured and distributed in accordance with the Medical Marijuana Research Act that meets the changing medical, scientific, and industrial needs for marijuana.”.

SEC. 7. ARTICLE 28 OF THE SINGLE CONVENTION ON NARCOTIC DRUGS.

Article 28 of the Single Convention on Narcotic Drugs shall not be construed to prohibit, or impose additional restrictions upon, research involving marijuana, or the manufacture, distribution, or dispensing of marijuana, that is conducted in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), this Act, and the amendments made by this Act.

SEC. 8. DEFINITIONS.

(a) QUALIFIED MARIJUANA RESEARCHER.—In this Act, the term “qualified marijuana researcher” has the meaning given the term in section 303(f)(3) of the Controlled Substances Act, as added by section 2(d) of this Act.

(b) UPDATING TERM.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—

(1) in subparagraph (A), by striking “the term ‘marihuana’ means” and inserting “the terms ‘marihuana’ and ‘marijuana’ mean”; and

(2) in subparagraph (B), by striking “The term ‘marihuana’ does not” and inserting “The terms ‘marihuana’ and ‘marijuana’ do not”.

SEC. 9. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from

New Jersey (Mr. PALLONE) and the gentleman from Oregon (Mr. WALDEN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 3797.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 3797, the Medical Marijuana Research Act. In recent years, including in this most recent election cycle, many States have taken action to allow cannabis use. While States are moving ahead with this action, there is a significant need for more research about the use of cannabis products in these States and the safety of products on the shelves.

According to the National Conference of State Legislators, 36 States, as well as Puerto Rico, Guam, the U.S. Virgin Islands, and the District of Columbia have approved medical cannabis programs, while 15 States, the District of Columbia, Guam, and the Northern Mariana Islands have approved adult-use cannabis. This is a major shift in cannabis policy, and the United States is not the only one making these changes.

Just last week, in a vote by the United Nations Commission on Narcotic Drugs, the body acknowledged the medicinal and therapeutic potential of cannabis and removed it from the most restrictive classification category. While still voicing a need for control, the United States voted in favor of this move, stating that the legitimate medical use of cannabis has been established through scientific research.

Unfortunately, American researchers seeking to study the products widely available and used by consumers in these States and territories face restrictions and numerous hurdles created by U.S. Federal policy. It is time we break through this catch-22. This bipartisan bill begins to address this issue by reducing barriers to cannabis research.

In January, the Committee on Energy and Commerce heard from Federal officials about the difficulty researchers face when it comes to conducting research with cannabis. As an example, for years, there has been only one source of marijuana made available by the University of Mississippi that can be used in the U.S. for research purposes. Another difficulty is that the current Federal registration requirements can be time-consuming and add unique and additional responsibilities than what is required for other types of medical research.

The Council on Governmental Relations, an association of research uni-

versities and other entities, says that this more cumbersome process often requires 6 to 12 months to complete.

In testimony before our committee on this bill, Dr. Nora Volkow, who is the director of the National Institute on Drug Abuse, underscored this point. She testified that barriers in the current process “present challenges to advancing cannabis research.” As a result, she said, we have a gap in our understanding of cannabis products on health.

Mr. Speaker, now this bill, H.R. 3797, addresses some of these barriers by streamlining the registration process for those who want to advance cannabis research. The bill does this while still maintaining appropriate oversight from both the Department of Health and Human Services and the Drug Enforcement Administration.

This bill also requires HHS and DEA to act within specified time periods to ensure timely registration for researchers, and it encourages additional manufacturers and distributors to supply cannabis for purposes of research. This will diversify the range of products and make it easier for legitimate researchers to obtain products that better reflect the changing cannabis landscape.

Mr. Speaker, finally, the bill would also promote research on cannabis products available through State-authorized programs. This additional research is critical if we are to better understand the benefits and risks of cannabis products available in State markets today and most frequently used by consumers.

Mr. Speaker, I thank the lead sponsors of this bipartisan legislation, Representatives BLUMENAUER, HARRIS, LOFGREN, GRIFFITH, BISHOP, and DINGELL, and their staffs, for their tireless work. I also thank the committee staff for their hard work, as well as the staff for both HHS and DEA for their technical assistance.

Mr. Speaker, again, I urge my colleagues to support this bill. I hope the Senate will act on it swiftly, and I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,

COMMITTEE ON THE JUDICIARY,

Washington, DC, December 7, 2020.

Hon. FRANK PALLONE, Jr.,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR CHAIRMAN PALLONE: This is to advise you that the Committee on the Judiciary has now had an opportunity to review the provisions in H.R. 3797, the “Medical Marijuana Research Act of 2019,” that fall within our Rule X jurisdiction. I appreciate your consulting with us on those provisions. The Judiciary Committee has no objection to your including them in the bill for consideration on the House floor, and to expedite that consideration is willing to forgo action on H.R. 3797, with the understanding that we do not thereby waive any future jurisdictional claim over those provisions or their subject matters.

In the event a House-Senate conference on this or similar legislation is convened, the Judiciary Committee reserves the right to request an appropriate number of conferees to address any concerns with these or similar provisions that may arise in conference.

Please place this letter into the Congressional Record during consideration of the measure on the House floor. Thank you for the cooperative spirit in which you have worked regarding this matter and others between our committees.

Sincerely,

JERROLD NADLER,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
Washington, DC, December 7, 2020.

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Chairman, Committee on Energy and Commerce,
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Sincerely,

JERROLD NADLER,
Chairman.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today to express my support of H.R. 3797, the Medical Marijuana Research Act introduced by my colleague and friend from Oregon, Representative BLUMENAUER, my friend from Maryland, Representative ANDY HARRIS, among others.

I am sort of surprised we aren't taking this up at 4:20 in the afternoon rather than 2:10, but we will let history deal with that.

Mr. Speaker, Federally sanctioned research on marijuana is incredibly challenging. It is a schedule I controlled substance under the Controlled Substances Act, meaning that researchers seeking to investigate a drug have to work with the Department of Health and Human Services and the Drug Enforcement Administration to meet certain Federal requirements in order to conduct that research.

In addition, international obligations outlined in the United Nations drug control treaties impose requirements that impact the supply of research-grade cannabis. Currently, those conducting federally-sanctioned research can only study marijuana that is sourced through the National Institute on Drug Abuse's single DEA licensee: the University of Mississippi.

Unfortunately, that marijuana is chemically distinct from what is commercially available from State-legal

dispensaries, such as in my home State of Oregon.

What does that mean?

Well, it means that we have little to no data on the actual health impacts of products in States that have legalized cannabis for medical or recreational use.

States that have pursued marijuana legalization have largely done so in an information vacuum, with less understanding of what it does than virtually any nutritional supplement currently on the market, and with far less information than they have on legal substances that are easily abused, such as alcohol or tobacco. We don't even know at what point it is unsafe for marijuana users to drive. The THC levels that States have set for driving legal limits or for purposes of food consumption are simply arbitrary.

Mr. Speaker, in Oregon, for example, cookies infused with THC are limited to 5 milligrams of THC per serving, or 50 milligrams per package. Now, you go across the Columbia River to the great State of Washington, and their limit is 10 milligrams or 100 milligrams. So there is little to no scientific evidence to support either of these levels. We simply don't know.

Mr. Speaker, here is what we do know: There have been increases in cannabis-related poison control center calls, emergency room visits, and impaired driving incidents. Nationwide exposure in youth is increasing, with record numbers of 8th through 12th graders regularly vaping marijuana products.

So we need research that reflects the reality of what is on the market. Products containing CBD derived from the hemp plant have become commonplace across the country in pharmacies and health food stores, and even in fast food chains since hemp was removed from the CSA in the 2018 farm bill.

Now, these products often contain claims that they can effectively treat everything from depression and inflammation to cancer or Alzheimer's. However, none of these claims have been evaluated or approved by the FDA, meaning patients may be relying on the unsubstantiated claims of CBD products and foregoing other proven medical treatments.

Mr. Speaker, like cannabis, while there is potential for CBD to provide patient benefits, the research and science lag far behind the market and the agencies are simply struggling to catch up. Last week, the majority forced this Chamber to vote on the MORE Act, which completely removed marijuana from the list of scheduled substances under the Controlled Substances Act—among many other things in that bill—and they didn't have the data to justify this policy decision.

Not only was this legislation incredibly premature, it could also potentially put the U.S. in violation of international treaty obligations. Any discussion of de-scheduling must be preceded by a fuller understanding of the

potential risks associated with cannabis use, which we currently do not have. And the current research restrictions on fully studying cannabis have effectively created a catch-22 in the re-scheduling debate.

So evaluations by the FDA and the National Academies have both concluded that the lack of research is a significant factor in denying previous administrative rescheduling petitions. More research, better data, remain the critical first steps to any future policy discussions. Making it easier to research cannabis is common ground that I think we can all agree upon and pursue together.

Mr. Speaker, I thank my colleagues, and especially Representatives HARRIS and BLUMENAUER, for working tirelessly to bring us this bipartisan, commonsense legislation. This bill will help improve the marijuana research landscape and give consumers the information they need.

Mr. Speaker, I urge a "yes" vote on this measure, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I want to thank the gentleman from Oregon. He has really been out front in educating me, in particular, and so many of us, on the cannabis issue. I think without him, we would not see many States like my own leaning towards legalization.

Mr. Speaker, I yield 3 minutes to the gentleman from Oregon (Mr. BLUMENAUER), the prime sponsor of the bill.

□ 1415

Mr. BLUMENAUER. Mr. Speaker, I appreciate the gentleman's kind comments and cooperation. Working with the ranking member, working with Dr. HARRIS, we made real progress here.

Mr. Speaker, the cannabis laws in this country are broken, especially those that deal with research. It is illegal everywhere in America to drive under the influence of alcohol, cannabis, or any other substance. But we do not have a good test for impairment because we can't study it. Now, Dr. HARRIS and I don't necessarily agree on the efficacy of cannabis, but we agree that this is insane and that we need to change it.

At a time when there are 4 million registered medical cannabis patients, and many more who self-medicate, when there are 91 percent of Americans supporting medical cannabis, it is time to change the system. Our bill will do precisely that. We have a broad coalition of Members and organizations who support the bill, including those who do have concerns about cannabis.

Specifically, the bill will tackle two main issues: research licensing and manufacturing. For manufacturers, it requires the DEA to license outside of the NIDA monopoly so we can study the products Americans are using. For researchers, it shortens the timelines, reduces unnecessary security measures, and streamlines approval.

This bill will not only reduce barriers to medical research but all cannabis research. It is a narrow bill that fixes one of many broken cannabis laws.

I want to hasten to add that this in no way negates the need to move forward with other areas of legislation, like we did with the MORE Act. But this is sort of a foundational question. No matter where you are, there is no reason the Federal Government should impede this critical research.

One of the most moving moments I have had in the last 2 years working on this issue was in the backyard of a constituent in southeast Portland who brought together a half dozen families with children with extreme seizure disorder. The only thing that stopped those babies from being tortured was medical cannabis. They had to research it themselves. They had to formulate it themselves.

At Oregon Health and Science University, they told me: This works. We know it works. We could go to the street corner and buy something, but we legally can't do it.

Listening to those heartbreaking stories of the families, of what they had to do—they crossed their fingers. It sort of worked for them. But no family should have to do that.

We ought to get the Federal obstacles out of the way of simple, common-sense research. It will make a difference for families across the country. We need to move forward, so there is no unnecessary dispute about cannabis, and get the job done.

SUPPORT THE MEDICAL MARIJUANA RESEARCH ACT

DEAR COLLEAGUE: We write to encourage you to cosponsor our bill, the Medical Marijuana Research Act (H.R. 3797). Regardless of your stance on marijuana, we can all agree that there should not be onerous federal barriers to conduct research and access objective evidence as to the medicinal properties of marijuana.

Although more than two-thirds of Americans are living in states with legal marijuana programs, current federal law greatly limits researchers' ability to research this drug. This includes the overly burdensome registration process, redundant protocol reviews, lack of adequate research material and unnecessarily onerous security requirements. In fact, a 2017 National Academies of Sciences, Engineering, and Medicine report found that "research on the health effects of cannabis and cannabinoids has been limited in the United States, leaving patients, health care professionals, and policy makers without the evidence they need to make sound decisions regarding the use of cannabis and cannabinoids. This lack of evidence-based information on the health effects of cannabis and cannabinoids poses a public health risk." We could not agree more.

The Medical Marijuana Research Act will reduce many of the barriers to conducting legitimate medical marijuana research. First, the bill streamlines the burdensome and often duplicative licensure process for researchers seeking to conduct marijuana research, while still maintaining all necessary safeguards against misuse and abuse. Second, it addresses the woefully inadequate, both in quantity and quality, supply of medical-grade marijuana available for use in

such research. Finally, it requires, within five years of enactment, a report by the secretary of the U.S. Department of Health and Human Services on the status and results of the then-available body of research on marijuana.

Irrespective of where one falls on the ideological spectrum with respect to further legalization, we can all agree that the American people deserve to know what's going on with marijuana. The United States leads the world in biomedical research. It is therefore unconscionable that the federal government stands as the chief impediment to legitimate medical research that will ensure American physicians, patients, purchasers, and constituents have access to the information they need to make an informed decision about marijuana.

Sincerely,

EARL BLUMENAUER,
Member of Congress.

ANDY HARRIS, M.D.,
Member of Congress.

Mr. WALDEN. Mr. Speaker, I yield 3 minutes to the gentleman from Maryland (Mr. HARRIS), who has been a real leader on this and so many other healthcare-related issues.

Mr. HARRIS. Mr. Speaker, I thank you for your concern about addiction and all the problems. This is an ancillary problem that deals with that. I thank you for your concern about that.

I thank the chairman of the committee and the ranking member. This has been years in the making. I thank them for bringing this across the finish line.

I thank my cosponsor from across the aisle. The gentleman from Oregon is absolutely right. He and I will disagree, probably the most two people can disagree, about recreational marijuana. We agree 100 percent that we need to do this research and that we need this bill.

Now, because of the discussion about COVID and the vaccines and therapeutics for that, Americans realize how medical research has to be done and how important it is to be done. They expect purity, safety, and efficacy for anything that has a claim of a medical product.

Now, unfortunately, because of the public policy we have had in place with marijuana and its scheduling, this simply couldn't be done. The unfortunate consequence is that legislatures in general across the States, and, unfortunately, this legislature last week, took a ready-fire-aim approach: Let's go ahead and legalize it, even for recreational use, without a medical basis.

But I am only going to talk about medical marijuana. We need good studies. Understandably, because of current scheduling, we can't do it. I get it. I did research, as a physician, on drugs. You can't do it under the current scheduling, but we need to do the research.

As the chairman pointed out, Dr. Volkow, who has appeared before our committee many times, has said that the claims of medical usefulness are simply greatly exaggerated because we don't have the science. Many claims are made; very few are proven.

We don't tolerate that for other medications. We certainly don't tol-

erate it for COVID vaccines and therapeutics. We shouldn't tolerate it for medical marijuana. This research just simply hasn't been done, for a variety of reasons, most of which get cured by this bill.

Now, could medical marijuana be useful for PTSD for my fellow veterans? Absolutely. It might be useful. We have no idea.

What we have done is, instead, the public press has said it is useful for PTSD. That is not the way we treat medicine in this country. We actually do the research. Our veterans deserve for us to do this research.

It couldn't be done, because of the scheduling, because of the rules—the rules, by the way, that Congress made. This is on us. We shouldn't have taken so long to get to this point.

Could it be useful for non-neurogenic chronic pain? Yes, it might be, but I don't know. The last thing we should do to our chronic pain patients, as you know, Mr. Speaker, because of the problems with treating chronic pain, is make false promises to them about something.

If this works for it, oh, my gosh, that is great. We have a potential solution for part of our addiction problem. If it doesn't work, those people deserve to know.

The SPEAKER pro tempore (Mr. TRONE). The time of the gentleman has expired.

Mr. WALDEN. Mr. Speaker, I yield an additional 1 minute to the gentleman from Maryland (Mr. HARRIS).

Mr. HARRIS. Mr. Speaker, is it useful for that group? Is CBD useful for that group of pediatric patients with seizures? Yes, it sure is. Is it useful for people with glaucoma? Yes, it sure is. Is it useful for spasticity with multiple sclerosis? Yes, it sure is.

But there are 40 or 50 other claims that we don't know about. We deserve to know about it. Those claims are simply not founded on science.

Look, let's do the science. Let's see what medical marijuana is useful for. As a physician, anything it is useful for, I want to provide for patients. Let's do the science. Let's pass H.R. 3797.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Michigan (Mrs. DINGELL), one of our colleagues on the committee.

Mrs. DINGELL. Mr. Speaker, I rise in strong support of the Medical Marijuana Research Act, which would streamline outdated bureaucratic barriers and Federal roadblocks preventing legitimate medical research into the impacts of medical marijuana.

I, too, like my colleague, thank you for your leadership. I have a healthy fear of drugs, having lost a sister to a drug overdose, but there is just too much information we do not have.

We have seen dramatic changes in the legal status of marijuana at the State level. Almost 1 year ago to the day, sales of recreational marijuana began in my home State of Michigan.

Following multiple successful State ballot initiatives last month, medical marijuana is now legal in 36 States. However, the Federal framework for conducting marijuana research is decades old and has not kept pace with these changes.

Currently, as has been said by my other colleagues, scientists in the United States looking to conduct research on marijuana must contend with a heavy-handed, duplicative registration and licensure process that doesn't work. They are limited to using marijuana grown at a single location overseen by the National Institute on Drug Abuse at the University of Mississippi.

Collectively, this regulatory red tape greatly limits our understanding of the health impacts of marijuana and prevents qualified researchers from engaging in further study.

We are driving cars that NHTSA can't do the research they need to do about people driving while smoking. We should know that.

The Medical Marijuana Research Act will streamline this cumbersome process by preventing bureaucratic roadblocks on marijuana research registration applications. It will also direct the FDA to issue guidelines on the production of marijuana and ensure that adequate amounts are available for research.

The legislation also mandates a comprehensive review of the available body of research on marijuana by the Secretary of Health and Human Services 5 years after enactment.

I thank my colleagues—Congresspersons BLUMENAUER, GRIFFITH, LOFGREN, HARRIS, and ROB BISHOP—for all of their work on this. This does matter. We need answers. And I thank my chairman, who has been great about this.

I refuse to accept the fact that our Ranking Member WALDEN is leaving. He is a dear friend, and he has made so much of a difference. He has had very thoughtful input on this, as he does on everything.

Mr. Speaker, it is high time we modernize our Nation's Federal regulations to facilitate legitimate medical research into the impacts of marijuana, and I urge my colleagues to support this legislation.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

I thank the gentlewoman from Michigan for her kind comments and her leadership on this legislation.

Mr. Speaker, can I inquire how much time is remaining?

The SPEAKER pro tempore. The gentleman from Oregon has 11½ minutes remaining.

Mr. WALDEN. Mr. Speaker, I yield such time as he may consume to the gentleman from Virginia (Mr. GRIFFITH), an extraordinary leader on the Energy and Commerce Committee, a gentleman I refer to as our counsel on the committee. He is an extraordinary lawyer and incredible public policy initiator.

Mr. GRIFFITH. Mr. Speaker, I appreciate that this bill has made it to this level.

You know, Congress doesn't always work well, but sometimes it does. ANDY HARRIS and I were back here, about where he is sitting right now, having a discussion one day, because a lot of times, things get solved or issues come to a head because we are trying to solve problems for the American people.

I believe that there are many uses for medicinal marijuana. I don't support recreational use, but I support medicinal use. ANDY thinks that it goes way too far, as you heard him just say.

But the bottom line is, as we were discussing it, neither one of us could cite scientific research to support our positions. So, we agreed at that point that we would work together on our side of the aisle. And obviously, the gentleman from Oregon has been leading on this for many, many years, and he was going to lead on the other side. We agreed we would try to find language that worked.

We have tried some backdoor routes to get it through some Energy and Commerce bills before, schedule 1R to do research. But this is extremely important. And you are either for medicinal marijuana or against medicinal marijuana, but you can't make an argument either way without the proper research.

This fine piece of legislation that was hammered out over a couple of years, maybe as many as 5 years, is a good piece of legislation, and it deserves the unanimous support of this United States House. I recommend it to each and every one of you.

That being said, I would like to take another minute to speak about my relationship with my Ranking Member WALDEN, who is leaving us. It is with regret on my part that he is leaving. He has a life to lead, and that is what people sometimes forget about Members of Congress.

There is life after Congress, and he is going to do some interesting things. I am anxious to learn what they are. He says he is anxious to learn what they are, too.

But he has so much talent. He has led our committee and then our side of the aisle on the committee so well, and has allowed those of us who are a little different sometimes to have some interesting ideas, to have those ideas bubble up, to take some interesting votes sometimes in committee, to allow Members down dais to have significant input. I am greatly appreciative of that.

I am also appreciative of his friendship and loyalty. I remember when we discovered that his longtime friend Ray Baum had a fatal disease, how he stuck with him, how Ray kept coming to work and was doing things all the way through, and then how he passed an important piece of legislation which commemorated all of Ray Baum's work.

The bill has Ray Baum's name on it, as it should, but it was a tribute from his friend, and I respect that type of friendship. I appreciate it very much.

I will always hold you in high regard. If I can do anything to be of assistance in the future, I will gladly do so.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to thank my friend and colleague from Virginia for not only his very kind comments but also his incredible work ethic.

I will tell one quick story about MORGAN GRIFFITH. I had a little bill, a suspension bill, that Mr. BLUMENAUER and I had to do a land exchange up on Mount Hood. It flew through here one night, first night of votes, and got two dissenting votes. One of them I understood, but his dissenting vote I didn't understand.

I went up to him, and I said: I am going to win this. There are only two noes. But why did you vote no?

He said: Well, I read the bill, and it referenced this memorandum of understanding between the Forest Service and Mount Hood Meadows about this land exchange. I tried to get a copy of that MOU, and I couldn't get it before I voted on the bill, so I voted no.

□ 1430

Well, the bill didn't get through that Congress. It got through the House, but not, of course, the other body.

So the next Congress, we did it again, and I made sure that Mr. GRIFFITH had that memorandum of understanding related to this little land transfer bill in an area that Mr. BLUMENAUER and I share, and he voted with us on that measure.

I thought: He is a pretty darn good, thorough legislator if he is reading every suspension bill and every land transfer bill and diving into the weeds. Americans need to know what a great man he is.

Mr. Speaker, I yield such time as he may consume to the gentleman from Georgia (Mr. CARTER).

Mr. CARTER of Georgia. Mr. Speaker, I rise in support of the Medical Marijuana Research Act.

Cannabis has been known by humans for thousands of years, yet we still don't truly know if the plant is medically beneficial. Some preliminary findings have given cause to believe that there may be some medicinal benefits. In fact, the FDA has authorized use of medical-grade CBD products for rare forms of epilepsy, but large-scale research has not occurred.

Despite this, more than half of the States have legalized cannabis for medical purposes. Even Georgia, my home State, has acted to expand cannabis laws.

As the legal status of cannabis evolves, we must prioritize making the plant available for medicinal research.

In 2017, the National Academy of Medicine found that there are several challenges and barriers in conducting cannabis and cannabinoid research, including the classification of cannabis

as a schedule I substance and the difficulty for researchers to gain access to the quality and quantity of product necessary for research.

I do not believe that the Federal Government should be standing in the way of medical research for cannabis products. Cannabis could be a lifesaving product. It may also not be, but we owe it to the patients to do the due diligence, research, and testing so that they may make the best medical decisions for themselves.

While we may all have differing opinions on the decriminalization of recreational marijuana—and my stance on that is well-known and well-documented that I am adamantly opposed to the recreational use of marijuana—I think we can all agree that we should facilitate better research on the plant's medicinal benefits.

Mr. Speaker, I am glad to see this legislation come to the floor for a vote. I thank my colleague, Mr. BLUMENAUER, for working on this legislation with me. I urge passage of this legislation.

Mr. Speaker, before I leave, I want to pay homage, if you will, to Mr. WALDEN, who will be leaving us, you have heard other speakers indicate before.

I came on this committee 4 years ago. Being the only pharmacist in Congress, I wanted to be on the Health Subcommittee, and I wanted to work in that arena. That is where Energy and Commerce was.

I will have to be quite honest with you. I really didn't understand just what a great committee—the best committee in Congress—Energy and Commerce is, and I truly believe that. I understand that now.

But I want to thank GREG WALDEN, because when I came in 4 years ago, he was the chairman of this committee, and he was very encouraging to me. In fact, he was my mentor on this committee. He led me and gave me opportunities, and I appreciate that very, very much.

His diversity, his intelligence, his fairness has been outstanding. His leadership has been outstanding, and it is only surpassed by his impeccable character.

Mr. Speaker, as he leaves, I want him to know how much I personally am appreciative of all of his help and all of his leadership.

Our committee, our Congress, our country is better off because of your work. Thank you and Godspeed.

Mr. WALDEN. Mr. Speaker, I want to thank my dear friend and colleague from Georgia (Mr. CARTER) for his leadership on so many issues before the committee and for his very kind and generous words. I will miss serving with Mr. CARTER. He has been a terrific member of the committee, and he, too, will have a great future ahead.

Mr. Speaker, our next Member, I should call him the deputy mayor of Washington, D.C., because that is kind of what you are when you are the ranking member of the House Administra-

tion Committee. He has been a passionate advocate on the next bill, but because of a meeting he has coming up, I am going to yield to him now, so he can make that scheduled appointment, to talk about this bill and the next bill.

Mr. Speaker, I yield such time as he may consume to the gentleman from Illinois (Mr. RODNEY DAVIS).

Mr. RODNEY DAVIS of Illinois. Mr. Speaker, I do support the bill that we are talking about. I have been a long-time supporter of medical marijuana use, and I certainly believe that the bipartisan legislation that is being put forward today is a great idea.

But it is also great to follow my favorite legalized drug dealer here at the dais, BUDDY CARTER, the only pharmacist in Congress. This is a guy who says a lot of things about GREG WALDEN. All of them are true, but I am going to get to that in a bit.

Mr. Speaker, I am here to thank my good friend, DONALD PAYNE, Jr., for allowing me to cosponsor a bill that is very personal to me, and that is the Removing Barriers to Colorectal Cancer Screening Act of 2020.

As some of you may know, my wife was diagnosed with early-onset colorectal cancer in 1999. She was 26 years old, and she is a 21-year cancer survivor today. It is a genetic form of cancer, Lynch syndrome, that I hope and pray that families like mine and many others don't have to continue to fight.

But it is imperative that we catch cancer in its early stages, and I can speak from experience, with my wife constantly being misdiagnosed just a few short years ago, and that is exactly what this legislation does for our Medicare population.

Put simply, this legislation ensures that, if a Medicare beneficiary receives a colonoscopy, which is covered by Medicare, he or she won't be billed for any subsequent tests on polyps that may be discovered during the screening.

The current policy of providing colonoscopies at no cost to beneficiaries but then billing them for potential findings, that greatly disincentivizes vulnerable individuals from actually seeking the screening process, which could lead to worse cancer and possibly death.

This is a commonsense fix that will save lives. I am proud to colead it, again, with my good friend, Mr. PAYNE. This is bipartisan.

But before I close, I want to take a moment to thank the countless advocates who have visited my office to fight for increased screening, including those with Fight Colorectal Cancer and the American Cancer Society. Today's vote stands as a testament to their advocacy and hard work.

Mr. Speaker, I want to thank, again, Chairman PALLONE and Ranking Member WALDEN and everyone on the Energy and Commerce Committee and the Ways and Means Committee for working with us to move this legislation forward.

Mr. Speaker, I urge my colleagues to vote "yes."

Mr. Speaker, now I do want to take some time—it is actually ironic to watch all of the well wishes to GREG WALDEN.

After first meeting him on an airplane that happened to land at the wrong airport, I didn't have a lot of high hopes for you, Mr. Ranking Member. I mean, who lands at the wrong airport, except an airplane that GREG WALDEN is on?

Unlike a lot of folks that are here touting what you have done, I say: Good riddance. It is about time.

In all seriousness, my friend, this place is going to miss you. This place is going to miss your humor. This place is going to miss your leadership and your tenacity. I can't tell you how proud I am to not just call you my colleague, but my friend.

Thank you for everything you have done for me and what you have done for this great institution. It is a better place because you served here, and it will not be as good a place without you here.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to thank my friend from Illinois for his generous comments and his great leadership, and I wish him well in the future.

Mr. Speaker, I urge passage of the underlying bill, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I ask for support to pass this legislation, and I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 3797, the Medical Marijuana Research Act. I advanced this bipartisan bill through my Health Subcommittee and I'm proud to support it on the Floor today.

According to the Department of Health and Human Services National Survey on Drug Use, 44 million Americans reported using cannabis in the past year. Thirty-three states now allow the medicinal use of cannabis and 11 states and the District of Columbia have legalized cannabis for adult use.

But state laws and federal policy are a thousand miles apart. As more states allow cannabis, the federal government still strictly controls and prohibits it, even restricting legitimate medical research.

The Medical Marijuana Research Act addresses these restrictions on research and alleviates a burdensome, out-of-date process for scientific researchers. First, it creates a new, less cumbersome registration process specifically for marijuana, reducing approval wait times and costly security measures. Second, this bill makes it easier for researchers to obtain the cannabis they need for their studies through reforms in production and distribution regulations.

Under this bill, scientists will no longer be forced to wait more than a year to become federally-approved to conduct cannabis research. They will also not be forced to use the cannabis grown by a government-authorized farm at the University of Mississippi. This cannabis lacks the properties and potency of commercially-available cannabis and leads to inadequate research.

This is a commonsense bill that will update federal policy to advance research on cannabis and its compounds. I urge my colleagues to support this bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 3797, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

REMOVING BARRIERS TO COLORECTAL CANCER SCREENING ACT OF 2020

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1570) to amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1570

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Removing Barriers to Colorectal Cancer Screening Act of 2020”.

SEC. 2. WAIVING MEDICARE COINSURANCE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in the second sentence, by striking “section 1834(0)” and inserting “section 1834(o)”;

(2) by moving such second sentence 2 ems to the left; and

(3) by inserting the following third sentence following such second sentence: “For services furnished on or after January 1, 2022, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.”.

(b) SPECIAL COINSURANCE RULE FOR CERTAIN TESTS.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)(1)(Y), by inserting “subject to subsection (dd),” before “with respect to”; and

(2) by adding at the end the following new subsection:

“(dd) SPECIAL COINSURANCE RULE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.—

“(1) IN GENERAL.—In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection (a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the

amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

“(2) SPECIFIED PERCENT DEFINED.—For purposes of paragraph (1), the term ‘specified percent’ means—

“(A) for 2022 and 2023, 80 percent;

“(B) for 2024 and 2025, 85 percent;

“(C) for 2026 and 2027, 90 percent; and

“(D) for 2028 and 2029, 95 percent.”.

(c) CONFORMING AMENDMENTS.—Paragraphs (2) and (3) of section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) are each amended—

(1) in subparagraph (C)(ii), in the matter preceding subclause (I), by striking “Notwithstanding” and inserting “Subject to section 1833(a)(1)(Y), but notwithstanding”; and

(2) in subparagraph (D), by striking “If during” and inserting “Subject to section 1833(a)(1)(Y), if during”.

SEC. 3. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w-3a) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting “or subsection (f)(2), as applicable” before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting “or subsection (f)(2), as applicable,” before “determined by”; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting “or subsection (f)(2), as applicable,” before “determined by”; and

(2) in subsection (f)—

(A) by striking “For requirements” and inserting the following:

“(1) IN GENERAL.—For requirements”; and

(B) by adding at the end the following new paragraph:

“(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

“(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning with the second calendar quarter beginning on or after the date of the enactment of this paragraph, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

“(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

“(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer’s average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under

this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

“(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

“(ii) to permit the Comptroller General of the United States to review the information provided; and

“(iii) to permit the Director of the Congressional Budget Office to review the information provided.”.

(b) ENFORCEMENT.—Section 1847A of such Act (42 U.S.C. 1395w-3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking “IN GENERAL” and inserting “MISREPRESENTATION”;

(B) in subparagraph (B), by striking “subparagraph (B)” and inserting “subparagraph (A), (B), or (C)”;

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

“(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of \$10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

“(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.”; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting “, except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.”.

(c) MANUFACTURERS WITH A REBATE AGREEMENT.—

(1) IN GENERAL.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)) is amended by adding at the end the following new sentence: “For purposes of applying clause (iii), a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under this part as a drug or biological.”.

(2) TECHNICAL AMENDMENT.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is amended by striking “section 1881(b)(13)(A)(ii)” and inserting “section 1881(b)(14)(B)”.